IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 04-940 (JJF)

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO PLAINTIFF'S MOTION IN LIMINE TO STRIKE THE "EXPERT REPORT OF JESSE DAVID, PH.D".

July 6, 2006

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Josy W. Ingersoll (#1088)
Adam W. Poff (#3990)
The Brandywine Building
100 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
(302) 571-6600
apoff@ycst.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

OF COUNSEL:

James Galbraith
Maria Luisa Palmese
A. Antony Pfeffer
KENYON & KENYON LLP
One Broadway
New York, NY 10004-1007
(212) 425-7200

TABLE OF CONTENTS

PAGES

TABLE OF AUTHORITIES

PAGES

Cases

Statutes

Teva Pharmaceuticals USA, Inc. ("Teva USA") submits this brief in opposition to Procter & Gamble's ("P&G's") motion to strike the expert report of Teva USA's expert Dr. Jesse David ("P&G Mot."). Dr. David's report was submitted to rebut the opinions of P&G expert, Dr. Smith, on the issue of "commercial success." Even though P&G bears the burden of establishing commercial success, P&G did not submit Dr. Smith's report until the date set for rebuttal reports. Since Dr. David is rebutting opinions in a rebuttal expert report, it was impossible for Teva USA to submit his report until after receipt of that report. Dr. David's testimony will relate entirely to his opinions, as an economist, about the economic issues raised in Dr. Smith's report, specifically the economic import of the sales of the patented product on the issue of obviousness. Under the circumstances, Dr. David's report was timely. Moreover, P&G can point to no prejudice caused by the timing of the submission. P&G has failed to establish the elements required by Third Circuit law to justify the exclusion of Dr. David's report and testimony.

BACKGROUND

P&G knew that Teva USA intended to challenge the validity of the asserted claims of U.S. Patent No. 5,583,122 ("the '122 patent") for obviousness under 35 U.S.C. §103, even before it filed the complaint. That defense was described in detail in Teva USA's Paragraph IV certification which triggered this action, and in Teva USA's answer to the amended complaint. (*See* Teva USA's Patent Cert. Notice (attached hereto as Exhibit A), at TEVA R 6089 – 92; D.I. 8, Teva USA's Answer to P&G's First Am. Compl., Oct. 4, 2004.) Additionally, Teva USA made clear its reliance on this defense in its interrogatory responses.

Notwithstanding Teva USA's reliance on the defense from the beginning, throughout fact discovery P&G never provided any details of its commercial success contention. In its interrogatory responses during litigation, P&G's only statements regarding non-obviousness due to commercial success were that "Because of Risedronate's surprising properties, it has achieved extraordinary commercial success, with sales of more than $2 billion since it came on the market in 1998." (P&G Supp. Resp. to Teva USA Interrog. No. 10, Oct. 5, 2005 (attached hereto as Exhibit B).)

The scheduling order in this case contemplated two rounds of expert reports. By agreement, the first round of expert reports, on issues which a party bore the burden of proof, were due on January 26, 2006. By agreement, the second round of reports, in rebuttal to the January reports, were due on March 10, 2006.

Despite bearing the burden on the issue of commercial success, P&G did not serve an expert report on this topic during the first round of expert reports in January 2006. Instead, it was only as rebuttal expert report that the detailed bases for P&G's contentions of commercial success were laid out. In rebuttal to this late expert report, Teva USA served P&G with the Expert Report of Dr. Jesse David, Ph.D. on April 12, 2006. Thus, P&G has had three months to consider Dr. David's five-page report. P&G cannot seriously complain that it has been prejudiced in any way by the timing of that submission.

ARGUMENT

I. P&G HAS FAILED TO PROVE THE ELEMENTS NECESSARY TO EXCLUDE DR. DAVID'S EXPERT REPORT AND TESTIMONY

In its motion, P&G has not addressed, much less established, the factors the Court must consider in deciding whether to exclude Dr. David's testimony. The Third Circuit

has stated that "the exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977) (citations omitted). "The Third Circuit has, on several occasions, manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony." *ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996). In this case, P&G has made no showing of neglect, bad faith, or flagrant disregard of the scheduling order.

A court in this circuit deciding whether to exclude evidence for failure to comply with a discovery order should examine the following criteria:

> (1) the prejudice or surprise in fact of the party against whom the excluded witness would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791 (3d Cir. 1994) (citing *Pennypack* and applying the "*Pennypack* factors").

A. *P&G Cannot Establish That It is Prejudiced or Surprised by Dr. David's Proposed Testimony*

P&G cannot contend that it did not know that Teva USA would argue that the alleged commercial success of Actonel is insufficient to overcome the primary evidence of obviousness in this case. Nor does the submission of the report in April, three months ago, prejudice P&G. Dr. David's testimony is narrow in scope and is directed solely to the issue of whether an adequate nexus exists between the alleged commercial success and the validity of the claims. P&G's own motion notes Dr. David's report is quite

narrow, and does not contain new data or numerous references. (*See* P&G Mot. at 4). All that would be necessary for P&G to prepare for trial would be to take Dr. David's deposition, which P&G has declined to do.

B. ***P&G Has Not Attempted To Cure Any Alleged Prejudice***

After serving the expert report of Dr. David on P&G, Teva USA offered to make him available for deposition at P&G's convenience. Instead of taking this deposition, P&G stated that it would file a motion to preclude his testimony. It then waited two months, until June 19, 2006, to do so.

Thus, any alleged prejudice is a self-inflicted wound. In any event, it can be cured by the simple chore of taking Dr. David's deposition. Although P&G has declined to take Dr. David's deposition thus far, there remains ample time to do so, since no trial date has been set.

C. ***P&G Has Not Established That Admitting This Evidence Will Disrupt the Orderly and Efficient Trial of This Case***

P&G has provided no evidence that allowing Dr. David's testimony will in any way disrupt the orderly and efficient trial of this case. There is no evidence that a delay of trial would be necessary. P&G has had Dr. David's expert report for more than two months, and has had ample opportunity to review all five pages of his report.

D. ***P&G Has Not Shown Any Bad Faith or Willfulness on Teva USA's Part in Submitting Dr. David's Expert Report***

P&G's motion to strike centers heavily on the fact that Dr. David's report was filed after the time set forth in the scheduling order for rebuttal reports. However, the facts make clear that this was not a bad faith or willful disregard for the scheduling order

in this case.[1] Instead, P&G failed to provide an expert report addressing commercial success—an issue on which they bore the burden of proof—until the rebuttal period. *See, e.g., Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (outlining the burden of proof on the patentee when asserting commercial success as evidence of nonobviousness). The scheduling order in this case called for expert reports on the issues which the parties bore the burden of proof to be filed first, followed by rebuttal reports on those issues. Since P&G did not file an expert report establishing the existence of commercial success until the rebuttal stage, there was no opportunity for Teva USA to provide a rebuttal expert report during the rebuttal stage.[2] Accordingly, Teva USA timely provided to P&G the expert report of Dr. David to rebut the expert testimony of Dr. Smith, and served it on P&G on April 12, 2006.

---

[1] This entire dispute arises due to the lack of complementarity between the three-part burden-shifting framework for presenting obviousness arguments, and the two-part schedule for filing expert reports in this case. P&G sets out the three-part obviousness framework on pages 6-7 of its supporting memo, and cites that framework as its reason for filing Dr. Smith's report during the rebuttal period. However, under the scheduling order as set out in its supporting memo, P&G left no opportunity in the briefing schedule for Teva USA to rebut Dr. Smith's report. This is not the first time that a court in this circuit has faced this problem within the obviousness framework. In *ABB Air*, the patentee, like P&G here, filed an expert report addressing "secondary considerations" during the rebuttal period. 167 F.R.D. at 672. Rather than file a rebuttal report, the alleged infringer moved to strike the patentee's expert report on "secondary considerations" arguing that the patentee had the burden of proof on that issue and filed the report during the rebuttal period. *Id.* Noting the lack of complementarity between the scheduling order and the burden-shifting framework, the court declined to strike the patentee's expert report and gave the alleged infringer the opportunity to rebut that report. *Id.* at 673. In the same vein, this Court should not strike Dr. David's report here.

[2] In its brief, P&G asserts that it did not serve its own expert report on commercial success in the initial exchange because it could not do so as it was a rebuttal to Teva USA's report on obviousness. Following this logic, Teva USA could not have submitted an expert report rebutting P&G's assertion of commercial success, on which P&G bears the burden, until after P&G's expert report on commercial success had been served on Teva USA.

Thus, the party whose report was untimely was not Teva USA, but instead was P&G. In its motion, P&G tries to excuse its tardiness by arguing that despite bearing the burden of showing commercial success, it did not have to submit a report on this issue at the time that expert reports were due for issues which the parties bore the burden of proof because Teva USA had not yet made a *prima facie* case of obviousness. This argument is nonsense. Teva USA, since prior to the onset of this litigation, has alleged that the claims of the '122 patent are obvious in light of the prior art. In fact, P&G's own interrogatory responses establish that it was well aware that Teva USA was alleging that the claims of the '122 patent were invalid for obviousness. Instead, P&G made a calculated decision to submit Dr. Smith's report in a manner that would effectively preclude Teva USA's ability to rebut Dr. Smith's testimony on an issue for which P&G bore the burden of proof. If this motion is granted, then P&G's manipulation of the scheduling order would succeed. If this motion is denied, then both sides would have the opportunity to present expert testimony on the issue of commercial success.

II. DR. DAVID WILL PROVIDE EXPERT TESTIMONY AS AN ECONOMIST

P&G also attacks the relevance and weight of Dr. David's testimony. While P&G does not dispute that Dr. David may be an expert on economic issues, it argues that Dr. David is not providing any useful expert testimony on economics, but instead will be providing his opinion on case law, and will effectively be a legal expert.

Dr. David's report makes clear that he will not testify as a legal expert, or presume to inform the court on what the law means. Instead, Dr. David will only provide his expert opinion as an economist, a subject on which he is amply qualified. Obviously, his testimony will be framed by the dictates of the case law as he understands it, and

hence the citations to some of the case law providing the framework for his testimony. This is the same as technical experts testifying on the issue of obviousness and relying upon their understanding of the law of obviousness. Just as that reliance does not convert a technical expert's testimony into legal testimony, Dr. David's reliance on his understanding of the law regarding the economic aspects of obviousness does not convert his economics expert testimony into legal testimony.

Dr. David's testimony, as set forth in his expert report, is that there was no economic incentive for anyone to combine the teachings of the '406 patent with the prior art because nobody with the requisite economic incentives had knowledge of the teachings of the '406 patent. Accordingly, Dr. David provides his opinion, as an economist, that any alleged commercial success of Actonel does not provide economic evidence that the claimed invention would not have been obvious. The relevance of commercial success as an objective indicia of nonobviousness rests heavily on economic underpinnings. Dr. David's testimony is strictly related to analyzing the economic realities in this case with respect to those economic underpinnings so the Court can apply these economic realities.

For the reasons set forth above, P&G's motion in limine to strike the "Expert Report of Jesse David, Ph.D." should be denied.

Respectfully submitted,

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (#1088)
Karen L. Pascale (#2903)
Adam W. Poff (#3990)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391
(302) 571-6600
apoff@ycst.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

July 6, 2006

OF COUNSEL:

James Galbraith
Maria Luisa Palmese
A. Antony Pfeffer
KENYON & KENYON LLP
One Broadway
New York, NY 10004-1007
(212) 425-7200

CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on July 6, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

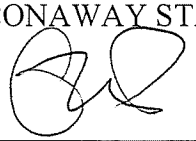
Frederick L. Cottrell, III, Esquire
Richards Layton & Finger
One Rodney Square
920 North King Street
Wilmington, DE 19801

I further certify that on July 6, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL AND FEDERAL EXPRESS

William F. Lee, Esquire
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Adam W. Poff (No. 3990)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
apoff@ycst.com

Attorneys for Teva Pharmaceuticals U.S.A., Inc.